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SUPPLEMENTATION IN CANCER PATIENTS RECEIVING CHEMO OR CHEMO/RADIATION THERAPY: A MULTICENTRIC, RANDOMIZED PHASE II STUDY



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Introduction and objectives

The use of supplements in cancer patients is justified by the low food intake caused by several factors. However, supplementation could be affected by adverse events (AE) related to oncologic treatment and vice-versa. The aim of this study was to compare the safety and efficacy of supplementation with isolated whey protein, leucin and zinc (Immax®) during treatment of these patients.

Methods

Patients who had received at least 2 cycles of chemo/chemoradiation therapy in neoadjuvant, adjuvant or palliative setting, were randomly assigned to receive Immax® + nutritional counseling (NC) (arm A) or NC alone (arm B). NC was according to diary requirements of nutrients and calories (Harris-Benedict) and, in the arm A, calories from the Immax® completed the energetic requirements. The supplementation was prescribed by 4 weeks. AEs were classified according to CTC-AE NCI, v 4.0. Body weight, BMI and nutrition intake were captured on baseline and 4 weeks later in both arms.

Results

Eighty-five patients were included (50 females) with median age 57,7 y. After 4 weeks of supplementation, the median of caloric intake, body weight and BMI were not statistically different in both arms. In Arm A, the median of supplement intake was 81,8g/328kcal per day and protein ingested was statistically higher (pre: 65.09±31.47g and post: 82.07±32.04g; p = 0.006). The most common treatment related AE were nausea and vomiting and its incidences weren't statistically different between the arms. AE supplement related were vomiting (2 pt/4,6%); diarrhea (2 pt/4,6%).

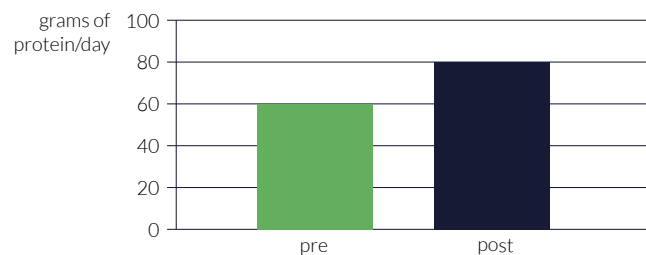


Figure 2: Protein intake pre and post supplementation with Immax®



Figure 1: meals prepared with Immax®

Conclusion

Immax® was safety and well tolerated by cancer patients and it didn't interfere with oncologic treatment. Immax® provided a significant protein intake in this patient population and its related AE were manageable.

Financial Support: Prodiel Clinical Nutrition

IMPACT OF ORAL SUPPLEMENTATION ON NUTRITIONAL STATUS OF PRE-CACHETIC PATIENTS UNDERGOING ONCOLOGIC TREATMENTS

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Purpose

Nutritional interventions are recommended to all malnourished cancer patients and those at nutritional risk, in order to prevent or reverse the decline in nutritional status and to prevent the progression to cachexia, marked by loss of muscle mass. Oral nutritional supplements (ONS) has been shown to increase energy and protein intake, with consequent benefit for nutritional status, especially when it is started early. In this context, proteins and specific amino acids as L-leucine are key nutrients to delay muscle degradation. The aim of this study was to evaluate the effect of a specialized ONS on the percentage of fat-free mass (% FFM) of pre-cachectic cancer patients undergoing chemotherapy.

Methods

Patients who had received at least 2 cycles of chemo/chemoradiation therapy in neoadjuvant, adjuvant or palliative setting and classified as pre-cachectic (PC) (ESPEN criteria), were randomly assigned to receive a high protein ONS enriched with L-leucine (Immax®, Prodiel Clinical Nutrition) + nutritional counseling (NC), henceforth demoted supplementation group (SG) or NC alone, the control group (CG). NC was according to daily requirements of nutrients and calories (Harris-Benedict). In the SG, calories from the ONS completed the energetic requirements. It was prescribed approximately 600 calories/d of the ONS for 4 weeks. Body weight, Body Mass Index (BMI), %FFM and nutrition intake were captured on baseline and 4 weeks later in both groups. The % FFM was assessed by bioimpedance before and after supplementation. Statistical evaluation was performed by analysis of variance (ANOVA), StatPlus 6.0 software.

Results

Fifty patients (36 women), 23 SG and 27 CG were included. The average intake of calories and protein (g) in SG pre supplementation was 1,679.22 (sd ±564.17) and 70.4 (sd ±30.10), respectively; in post supplementation the average intake was 1,865.19 calories (sd ±503.10) ($p > 0.05$) and 88.9g (sd ±24.05) of protein ($p = 0.026$). In CG the average intake of calories and protein (g) pre supplementation was 1,503.84 calories (sd ±518.82) and 65.69 (sd ±21.01), respectively, and in the post supplementation it was 1445.62 calories (sd ±518.80) and 72.09g (sd ±26.47) of protein ($p > 0.05$ for both). After intervention, the difference between the groups was statistically different for calories (419.57; $p = 0.005$) and protein (16.8g; $p = 0.024$). The average daily ONS intake was 400.4 calories in SG which contributed with 25g of protein and a total of 6.2g of L-leucine. The SG maintained the %FFM during the cancer treatment, and the mean of % FFM was 63.47% (SD ±6.17) pre supplementation and 65.86% (SD ±7.76) post supplementation, corresponding to an increase of 2.39% after intervention ($p = 0.25$). On the other hand, in the CG, this average was 65.32% (SD ±8.51) at the beginning of the study and 63.63% (SD ±7.37) after intervention, with an average drop of 1.69% ($p = 0.43$) in % FFM. The mean difference in % FFM after intervention between groups was 4.08% (95% CI 1.63-6.53; $p = 0.00157$).

Conclusion

The use of a specialized ONS enriched with L-leucine in the studied population proved to be efficient for maintaining fat free mass of patients during cancer treatment and increased the intake of calories and protein even with an isocaloric intervention protocol between the two groups. The % FFM gain was significantly higher in the SG Group, highlighting the importance of including a specialized high protein ONS in nutritional intervention of cancer patients.

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**Check the full publication of this clinical trial
in Nutrition and Cancer:**


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